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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 9

Application Number: 09/990,499
Filing Date: November 21, 2001
Appellant(s): BAKSHI ET AL.

Philippe L. Durette
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11 February 2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the issue for both sets of claims is the same. If claims 39-73 (drawn to methods of treating male erectile dysfunction with selective human MC-4R agonists) fall due to lack of enablement then claims 74-75 (directed to

oral methods for the treatment of erective dysfunction comprising the oral use of selective human MC-4R agonists).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 39-75 stand rejected under 35 U.S.C. 112, first paragraph. This rejection is set forth in prior Office Action, Paper No. 5, dated 9 August 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

The rejection of claims 1-38, now canceled and replaced with claims 39-75, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention, as stated in paper #2, dated 11 March 2002, is upheld. The specification does not enable the ordinary artisan to choose a compound that is other than patented in the parent case, namely a substituted isoquinoline. The entire specification is drawn to substituted isoquinoline compounds of formula (I) that are MC-4R agonists. There is no teaching in the specification that would lead one of ordinary skill in the art to compounds other than formula (I). Without a teaching of what other compounds to pursue, the specification is seen to be lacking in enablement for the instant claims. Without guidance, the instant specification is an invitation to test any and all known and unknown compounds for their ability to bind selectively and be agonists of MC-4R.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: *The claims are drawn to treatment of sexual dysfunction in a male subject with any compound that is a MC-4R agonist.*

2) The nature of the invention: *The invention is drawn to treatment of male erectile dysfunction by using a MC-4R agonist wherein the binding of the compound to MC-4R is characterized by an IC50 of less than 30 nanomolar and the binding of the compound to the human MC-1R is characterized by an IC50 greater than 30 nM.*

3) The state of the prior art: *The prior art discusses treating male erectile dysfunction by using certain families of compounds that are MC-4R, MC-3R, MC-2R, MC-1R, and MC-5R agonists. However, the art is silent about what other compounds or families of compounds might be MC-4R agonists.*

5) The level of predictability in the art: *It has not been shown that there is any level of predictability in the art.*

6) The amount of direction provided by the inventor: *The inventor has provided direction only for the compounds of formula (I) treating male erectile dysfunction. However, there is no direction provided by the inventor to treat male erectile dysfunctions with any compound that is other than a compound of formula (I).*

7) The existence of working examples: *The only working examples of MC-4R agonists are of formula (I).*

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: *The experimentation needed to make or use the instant invention is undue. There is no guidance of what kind of compound to choose other than of formula (I) to be a MC-4R agonist. The ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims. This is very extensive and undue experimentation.*

Taking these into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instant invention. The rejection of claims 39-75 is upheld.

(11) Response to Argument

First, Applicant argues that the examiner has misconstrued the nature of Applicants invention. The invention is not to a class of structurally defined compounds or methods of using a particular chemical compound or class of structurally defined compounds but to a specific physiological function for the human MC-4R, the link between MC-4R agonism and the induction of penile erections.

However, applicant is attempting to patent a method of treating male erectile dysfunction by using compounds to treat this condition. Applicant is not trying to patent the link between human MC-4R agonism and the induction of penile erection.

There is no statutory class of invention that covers a link between human MC-4R agonism and the induction of penile erection. Applicant states "Briefly, the Applicants have not invented compounds...".

Second, Applicant argues that selective activation of MC-4R can induce penile erections and consequently small molecule agonists of MC-4R have the therapeutic utility to treat male erectile dysfunction (MED).

However, as stated above, there is no statutory class of invention that covers the patenting of a link between the agonism of MC-4R and the treatment of MED.

Third, Applicant argue that the "critical reaction parameter" for the method claims is the function of selective activation of the human MC-4R and that Applicant's specification clearly set out a roadmap for the skilled artisan to follow.

However, this roadmap that Applicants give is not fully enabled by examples of working compounds, suggestions of compounds that might work, or even a place to start to look for compounds that work. The specification lacks enablement for the ordinary artisan to make a compound that would fulfill the instantly claimed invention.

Fourth, Applicants argue that the instant specification describes how to evaluate compounds therapeutic properties in several in vivo models of MED. The methods

used to identify selective binders of MC-4R are well within the skill of the ordinary artisan.

However, the ability to identify whether or not a compound is or is not within the scope of the instant claims is not in question. The ability of where the ordinary artisan would begin the search is the question. There is no enablement within the instant specification to teach the ordinary artisan where to start to look for compounds that would fall within the scope of the instant claims. What compounds would be promising to screen for this activity? What is the core of the group of compounds that would fulfill the instant claims? These are things that lack enablement and would require undue experimentation.

Fifth, Applicants argue that "A considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation sho8uld proceed".

However, the instant specification lacks a place to start this routine experimentation and lacks guidance with respect to the direction where the ordinary artisan should proceed.

Sixth, Applicants argue that the critical or essential method parameters which are necessary to the practice the invention are available in the specification.

However, the critical method parameters necessary to practice the instant invention are not the screening for the compounds but the identity of the compounds to be screened. Knowing the path is essential but critical to this path is knowing where the path starts.

Seventh, Applicants argue that the specification teaches one of ordinary skill how to identify selective MC-4R agonists and how to use them to treat MED.

However, the critical and essential thing that is not enabled is what compounds or class (Markush) of compounds to start with to put into these assays to identify which of these compounds or class of compounds are selective MC-4R agonists.

Eighth, Applicants argue that they have disclosed to the public a potentially medically useful approach for the treatment of erectile dysfunction based on a novel mechanism of action.

However, the only thing Applicants have disclosed is a link between human MC-4R agonism and the treatment of MED. Applicants have not disclosed what compounds or class of compounds would or might be used to treat MED. The ordinary skilled artisan needs direction and a starting point from which their ordinary skills can be used to practice an invention. The instant specification lacks this direction.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 16, 2003

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